REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

1. Examiner rejects claims 9, 12, 13 and 21 as being anticipated by George (USP 5,014,494).

Regarding Claim 9: Examiner states that George provides a sealable container for avoiding yellowing of plastic medical articles during gamma radiation sterilization. Applicants agree that yellowing discoloration can occur when certain materials are gamma sterilized in an oxygen-containing atmosphere. The methods suggested by George are directed to prevention of that yellowing discoloration and "increased brittleness" (column 1, line 62). Yellowing discoloration of a variety of materials can occur over time, depending on the materials, contact with gases, liquids, or solid materials, temperature, light, and so forth. The particular problem being addressed by George is preventing a very rapid or premature yellowing and increased brittleness which can occur within minutes during a gamma sterilization procedure. The present invention is directed to detecting the presence of oxygen within the sterilized package after sterilization. The present invention provides apparatus and methods for visually verifying that the medical device has not become "contaminated" by the presence of oxygen at any time, not simply avoiding yellowing during sterilization. While it is helpful to prevent yellowing of the medical products during sterilization, the present invention is directed to reliable detection of the presence of oxygen by the user of the medical products. In certain situations, it is important to detect the presence of oxygen in a medical device package, even if the medical device has not suffered significant yellowing or increased brittleness. Thus, George does not provide a sufficient solution to the problem by simply avoiding yellowing during the sterilization procedure. The present invention

provides apparatus and methods for visually detecting oxygen contamination of a medical device package even if such oxygen contamination occurred during shipment, storage, or other handling of the medical device package subsequent to sterilization.

Regarding Claim 12: Examiner states that George discloses that "if the container has failed and oxygen is let into the container, yellowing will occur in those plastics ...which yellow in the presence of oxygen post gamma radiation." Examiner is incorrect. The medical articles of George yellow during the sterilization process, when the medical articles are in an oxygen environment during gamma sterilization. Many of the relevant materials are much more susceptible to yellowing during gamma sterilization than they are in normal storage conditions. Therefore, George does not provide a solution for detecting oxygen which may have entered through a failure of the container after sterilization, because the materials may exhibit no significant yellowing when stored in oxygen for extended periods.

Regarding Claim 13: George cites polypropylene, silicone, and polyvinyl chloride materials; however, these materials yellow very slowly, if at all, when stored properly. George does not cite polycarbonate materials. The materials cited by George are medical devices which can deteriorate during gamma sterilization in oxygen. However, the oxygen-sensitive material of claim 13 (and claim 9 from which it depends) are visual indicator materials distinct from the medical product being stored in the package. George does not speak to this.

Regarding Claim 21: George does disclose "medical articles," specifically those which yellow or increase in brittleness during gamma sterilization in an oxygen environment. The present invention is not limited to medical products which show yellowing or increase in brittleness during gamma

sterilization in an oxygen environment. Claim 9, from which claim 21 depends, cites an oxygen-sensitive material distinct from an oxygen-sensitive product. In other words, the present invention utilizes an oxygen-sensitive visual indicator which is distinct from the medical product being stored in the package, whereas George cites medical articles which themselves yellow or increase in brittleness during gamma sterilization in an oxygen environment.

Therefore, George does not anticipate the present invention as claimed.

2. From the previous discussion, the present amended claim 9 is not anticipated by George, so obviousness of the dependent claims 11, 15-17, 19 and 20 should no longer be at issue. Nevertheless, Applicants offer the following.

Regarding Claim 11: Examiner states that "a piece" can be construed as a single medical device, which is what is disclosed by Nicolais. As is clear from amended parent claim 9, there are at least two distinct items in the package in the present invention: (1) an oxygen-sensitive product (such as a medical device), and (2) oxygen-sensitive material (which is a visual indicator of oxygen exposure). Thus, it would seem Nicolais would not apply, and George taken together with Nicolais does not render claim 11 obvious.

Regarding Claims 16 and 17: Examiner states that George discloses "impermeable containers using foil which are necessary for the sterilization in the absence of oxygen." That is not correct: a sterilzation chamber with a non-oxygen atmosphere would be sufficient to keep oxygen away from the medical product even if a permeable package were used according to the teaching of George. Further, the column 2, line 47, of George citation is discussing storage of the packaged medical product prior to sterilization, not preventing oxygen from entering the packaged medical product after sterilization which would be acceptable

for medical articles of George. The detection of oxygen in the package, even if it entered after sterilization, is the subject of the present invention. The particular laminate of claim 17 is an example of a configuration which can be utilized in the present invention advantageously, and is further limiting.

Examiner states that it would have been obvious to modify the container of George with the teachings of using a single medical device in the sealed container during sterilization, so that if oxygen is present and the device yellows, the situation will be easily visually identified. However, whether that is or is not the case is not relevant, because the present invention as claimed in claim 9 does not use a single medical device, but rather a medal product plus a distinct oxygen-sensitive material. Further, the container of George would provides for avoidance of yellowing during sterilization, not for detection of oxygen after sterilization such as if oxygen were to enter the package during storage or handling of the sterile packaged device.

Regarding Claim 15: The Ahlqvist et al. reference cites a gamma radiation dose for sterilization. However, claim 15 refers to a gamma radiation dose which is "an effective amount" for activation of the oxygen-sensitive polycarbonate, not an amount for sterilization. The reference does not cite activation of oxygen-sensitive material, and therefore does not render claim 15 obvious.

Regarding Claims 19 and 20: The cited times were meant to describe the speed of visual change if oxygen were to enter the package after sterilization; the immediate yellowing referred to by Examiner occurs during gamma sterilization in an oxygen atmosphere, but if one were to introduce oxygen after completing the gamma sterilization one would not ordinarily expect a rapid yellowing. Claims 19 and 20 are amended to clarify the meaning.

3. Examiner refers to George, Sleeckx, Funakoshi et al., and DeRudder et al. as evidence that it would have been obvious to use the sealable container of George with the polycarbonate plastic disclosed by Sleeckx to shield the polycarbonate from oxygen during sterilization to minimize yellowing. That, however, is not the point of the present invention. The present invention is directed to detection of oxygen in the package, even if oxygen entered the package after sterilization. The cited art is directed to preventing yellowing during sterilization. The present claim 14 provides even more utility, where the oxygen-sensitive material is not only a polymer of polycarbonate composition, but is activated by an effective amount of gamma radiation. This additional utility, where the oxygen-sensitive material will not function as an oxygen sensor until it is activated (see paragraph 22 of the present application), appears absent from the cited art. Thus, the cited art, taken together, does not render claim 14 obvious.

4. Examiner rejects claims 18 and 22 as obvious from George in view of Archey et al. and Lewis.

Regarding Claim 18: It is not clear from the Archey et al. reference whether ASTM D-1925 refers to testing of polycarbonate chips, or simply a standard yellowing test method which could be applied to any material. Applicants do not have the cited standard, but the American Society for Testing and Materials lists the title of ASTM D-1925 as "Test Method for Yellowness Index of Plastics" which suggests that the cited method could be used to evaluate a variety of polymers, rather than particularly materials which had been exposed to gamma radiation, not particularly polycarbonates. Nevertheless, Applicants did not suggest that they invented polycarbonate chips which yellow when gamma sterilized in oxygen. Rather, claim 18 cites a particular storage arrangement which utilizes a chip of oxygen-sensitive material with a backing material to enhance visibility of the

visual change in the oxygen-sensitive material upon exposure to oxygen. Since claim 9 is not anticipated by George, and the Archey et al. reference does not teach the particular arrangement cited in claim 18, George in view of Archey et al. does not render claim 18 obvious.

Regarding Claim 22: The Lewis reference is one example of utilizing a symbol to enhance visibility of an oxygen sensor. The combination of George and Lewis would lead one to a symbol which enhances visibility of an oxygen sensor which detects the presence of oxygen during gamma sterilization. Therefore, George in view of Lewis does not render claim 22 obvious.

As to Examiner's suggestion that thin planar chips would likely undergo yellowing quicker than the thicker materials used in medical devices, Applicants disagree. A thin chip would have a greater fraction of the material affected by oxygen in contact with the surface, but the absolute volume or thickness of material which yellowed might be the same for a thin chip as for a thicker object. It is not clear whether a thick object with a yellowed surface layer or a thin object with a yellowed surface layer (of similar thickness) would be more easily identified visually as having yellowed.

Regarding Examiner's Conclusion: Applicants did not intend to claim properties of polycarbonate. Applicants are claiming a particular storage arrangement which utilizes oxygen-sensitive material, which, in some claims, is a polycarbonate material, and which is located and utilized together with other components in a novel way.

Claims 9, 19 and 20 have been amended. Claims 23 and 24 have been added. No new matter has been added.

It is believed that the claims are now in condition for allowance.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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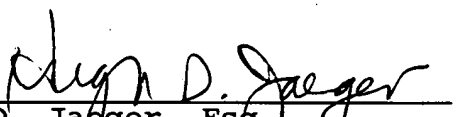

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